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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/155,023	09/21/98	GUILE	S 2257-137
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HM12/0928

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EXAMINER

KESSINGER, A

ART UNIT	PAPER NUMBER
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1611

DATE MAILED: 09/28/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/155,023

Applicant(s)
Guile et al.

Examiner
Ann M. Kessinger

Group Art Unit
1611



- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-14 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-14 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of References Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claims 1-14 are pending in the application.

Specification

The disclosure is objected to because of the following informalities: The nitrogen atom in Formula (III) on page 5 of the specification is tetravalent which would result in a positively charged nitrogen atom.

Appropriate correction is required.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119. However, benefit cannot be granted since none of the certified copies of the priority documents have been received in this national stage application from the International Bureau.

Claim Rejections - 35 USC § 112

Claims 1-7 and 9-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled

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in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The following reason(s) apply:

1. The claims are not commensurate in scope as to possibilities for the substituent “a fused 5- or 6-membered saturated ring containing one or two oxygen atoms” in the definition of R2. The specification’s definition is lacking for this term and thus it is open-ended and all encompassing. The cited examples are drawn only to R2 as 1,3-benzodioxolyl. The specification does not enable any person skilled in the art to make and/or use the invention commensurate in scope with these broad claims, which embrace a diversity of heterocyclic moieties in the R2 definition. The examples on pages 17-123 are drawn only to compounds with the aforementioned limitations. The specification is silent regarding the making and using of the additionally claimed compounds.

In cases directed to chemical compounds which are being used for their physiological activity, the scope of the claims must have a reasonable correlation to the scope of enablement provided by the specification. See *In re Surrey* 151 USPQ 724 regarding sufficiency of disclosure for a Markush group and *In re Wiggins* 179 USPQ 421. No reasonable assurance has been made that the instant hetero containing compounds as an entire class have the required activities needed to practice the invention.

2. The scope of “acyl” and “alkylsulfonyl” as recited in claim 1 for the definition of R12 and R13 reads on carbons of non-limiting length. Long chains would be difficult to prepare and may be too insoluble for instant uses. See *In re Hawkins* 179 USPQ 157 regarding carbon radicals that have unlimited chain lengths and ring sizes in the specification.

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Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reason(s) apply:

1. Scope of “a fused 5- or 6-membered saturated ring containing one or two oxygen atoms” for the variable R2 is unclear as to what is intended since the specification does not have a definition for this term. For example, is the fused ring saturated or unsaturated? How big is the fused ring? Specification gives no guidance to these answers. Furthermore, the definition is unclear to the array of heteroatoms as well as nature of atoms as ring members. “Containing” is open-ended and does not exclude additional, unrecited elements. See MPEP 2111.03. See *In re Wiggins* 179 USPQ 421 for claim terminology regarding heterocyclic ring systems.
2. In the definition of R1 in claim 1, “C2-C6alkenyl” is repeated twice.
3. Claim 2 is an independent claim and thus should be complete as written. Therefore, all of the R variables must be defined in the claim.
4. “C3-C8alkyl” as a possible substituent for the phenyl group of R2 in claim 4 is outside the scope of main claim 1 (from which claim 4 ultimately depends). C1-C6alkyl is recited as a possible substituent for the phenyl group of R2 in claim 1. If applicants’ intend to modify this substituent, they must illustrate that no new matter is being presented.
5. The scope of “solvates” is unknown. Specification provides no guidance as to what might be intended. In addition, applicants should note generally not all solvents can form solvates with all compounds.

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6. Claims 1 and 10-12 are duplicates as they each depend on claim 1. Different intended uses are given no material weight in such claims. Note *In re Tuominen* 213 USPQ 89.
7. Claim 13 is grammatically awkward. Note “treatment a platelet aggregation disorder” and “effective amount of a according to claim 1.” Correction is required.
8. Claim 14 is an independent claim and thus should be complete as written. Therefore, all of the R variables must be defined in the claim and thus should not be “as defined in formula (I)”.
9. Since a claim is one sentence, the examiner suggests deleting the bullets in claim 14 and inserting “or” between each optional step.
10. The carbon range for “acyl” and “alkylsulfonyl” as recited in claim 1 for the definition of R12 and R13 is not clear as to what is intended. Are C₁₀, C₁₀₀ carbons intended? Specification appears to give no guidance.
11. The nitrogen atom in Formula (III) in claim 14 is tetravalent which would result in a positively charged cation. A negative anion is not set forth to obtain neutrality and therefore cationic derivatives, and not compounds, are being claimed as final products.
12. In claim 8, page 130, the third from the bottom species is missing a bracket. Furthermore, the second to last compound on page 131 is misspelled. Note “phenoyphenyl”. Moreover, the third compound from the top of page 136 is misspelled. Finally, a parenthesis is missing in the last compound on page 137.
13. “Derivatives” in claim 14 imply more than what is positively recited.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 9-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Cox et al. Cox, WO 97/03084 (equivalent to U.S. Patent No. 5,747,496), teaches compounds of the instant invention useful in the treatment of platelet aggregation wherein R1 is trifluoropropyl, pentyl or propyl; R2 is hexyl, dimethylbutyl, butylmethoxyethyl, methylthioethyl or ethyl; R3 and R4 are both hydroxy and R is propanoic acid, propanoic acid ethyl ester, propenoic acid or propenoic acid ethyl ester. See Example 1 on page 29, Example 3 and 3a on page 34, Example 4 on page 35, Example 5 on page 38, Example 6 on page 39, Example 7 on page 40, Example 10b on page 43, Example 11a and 11b on page 45, Example 12a on page 46 and Example 13i on page 49, etc. Note instant process of preparing compounds of Formula (I) is also rejected herein. See Reaction Scheme B starting on page 10 and ending on page 13.

Claims 1-6 and 9-14 are rejected under 35 U.S.C. 102(a) as being anticipated by Bonnert et al. Bonnert, WO 98/28300, teaches compounds of the instant invention for use in the treatment of platelet aggregation disorders wherein R is COOH or CO(NH₂) or CO(NH)alkyl.

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See, for example, the many compounds listed on pages 15-78. Note instant process of preparing compounds of Formula (I) is also rejected herein. See the reaction scheme starting on page 10.

Double Patenting

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and © may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6 and 9-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 09/155,562. Although the conflicting claims are not identical, they are not

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patentably distinct from each other because the subject matter claimed herein overlaps with copending 09/155,562.

Claims 1-6 and 9-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 09/011,992 (U.S. equivalent to WO 98/28300). Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed herein overlaps with copending 09/011,992.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Commonly assigned WO 99/05142 (equivalent to U.S. Serial No. 09/155,562), WO 99/41254 and WO 99/05144 are all cited because they disclose similar subject matter to that claimed herein for the same uses. However, they are not competent references in view of their too late publication date. If the later two WO documents enter the National Stage, the examiner handling those cases should be informed as to the existence of this case. Commonly assigned documents are not being provided.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Kessinger whose telephone number is (703) 305-1878. The examiner can normally be reached on Monday thru Friday from 9:30 AM to 6:00 PM.

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

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All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Ann M. Kessinger 

September 23, 1999



Mukund J. Shah
Supervisory Patent Examiner
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